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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/296,040 04/21/99 DANEK

C 031201-025

EXAMINER

FARAH, A

ART UNIT	PAPER NUMBER
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3739

DATE MAILED:

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QM12/0314

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/296,040

Applicant(s)

Danek et al.,

Examiner

Ahmed Farah

Group Art Unit

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☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-54 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-54 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to the amended claims 1 and 46 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-12, and 14 -54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiggs et al., "On the mechanism of mucosal folding in normal asthmatic airways", The American Physiological Society, 0161-7569/97, in view of Laufer et al., U. S. Pat. No. 5,972,026.

Wiggs simulates the effect of smooth muscle shortening and also describes its effect on airway walls, as seen in asthma patients. In a detailed discussion, Wiggs teaches that the narrowing of the airways may cause airflow obstructions, thereby making it difficult for asthma sufferers to breathe. In addition, Wiggs describes that the magnitude of the obstructive response observed for a given degree of smooth muscle activation reflects the contractile capacity of the airway smooth muscle and the resistance to airway deformation due to the structural components

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of the parenchyma and airway wall. However, Wiggs does not teach a method of treating the narrowing of the airway walls by transferring energy to or from the airway walls.

Laufer et al., teaches a method and a device for treating subjects experiencing difficulty in breathing as a result of obstructed airway passages caused by chronic obstructive pulmonary disease and asthma. Laufer applies electromagnetic energy, such as radio frequency, directly into the tissues of the airway walls whereby said energy alters the structure and the functions of the airway walls in a manner similar to the claimed invention. Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to employ the teachings of Wiggs in view of Laufer's invention to prevent the narrowing of the airways in order to relief asthma patients from breathing difficulties.

4. Claims 6 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiggs et al., "On the mechanism of mucosal folding in normal asthmatic airways", The American Physiological Society, 0161-7569/97, in view of Laufer et al., U. S. Pat. No. 5,972,026 as applied to claim 1-5, 7-12, and 14-54 above, and further in view of Edwards et al., (U.S. Pat. No. 5,624,439).

Although Laufer et al., teaches a method of maneuvering a heating device into the lumen of the bronchial tube, neither Wiggs et al., nor Laufer et al., specifically describe a method of treating airway by moving energy transfer device along the airway.

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However, Edwards discloses a method and apparatus for treatment of airway obstructions comprising a first arm including a proximal end and a distal end, the first arm distal end is inserted into the throat and positioned adjacent to a back surface of the tongue. Edwards further teaches that a plurality of RF electrodes are positioned in the first arm wherein said electrodes are advanced into the back of the tongue and then retracted, as presently claimed, in order to alter the airway.

Therefore, it would have been obvious to one having the ordinary skill in the art at the time of the applicant's invention to modify the teachings of Wiggs et al., in view of Laufer et al., and in further view of Edwards and move the energy transfer device along the airway in order to reduce tissue inflammation and alter the function of the airway wall by altering its resting tone.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

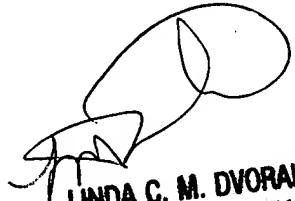
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following reference:

1) Erickson

U. S. Pat. No. 5,549,655

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703)305-5787.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Linda Dvorak, can be reached on (703) 308-0994. The fax number for this Group is (703)305-3590.



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SUPERVISORY PATENT EXAMINER
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